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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,506	05/10/2002	Robert Bartlett Elliott	GL216721-003	8690

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EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,506	ELLIOTT ET AL.	
	Examiner	Art Unit	
	Randall Winston	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0802*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claims 28-32, and the election of species of c) cardiovascular disease, in the reply filed on 09/14/2004 is acknowledged.

Examiner acknowledges that claims 1-27 and 33-36 are canceled. Claims 28-32 will be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant" must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is "*whatever is now claimed*" (see page 1117).

A review of the language of the claims indicates that claims are drawn to a genus of an "analogue of beta-casomorphin-9" and "precursor of beta-casomorphin 9".

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention".

There is a single species of the claims 28-32 genus disclosed within the specification that is within the scope of the claimed genus of an "precursor of beta-casomorphin-9". The specification on page 5 lines 130-131 discloses the single species such as "A2 beta-casein" that is within the claimed genus of a "precursor of beta-caspomorphin-9". There is no single species of the claims 28-32 genus disclosed within

the specification that is within the scope of the claimed genus an "analogue of beta-casomorphin-9).

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claims 28-32 encompass numerous species that are not further described. There is substantial variability among the species.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises of an "analogue of beta-casomorphin-9" and "precursor of beta-casomorphin 9".

The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 recites the indefinite terms of an "analogue of beta-casomorphin-9" and "precursor of beta-casomorphin 9". The metes and bounds of an "analogue of beta-casomorphin-9" or a "precursor of beta-casomorphin 9" cannot be delineated, as the specification fails to set forth the metes and bounds of what is encompassed. (please

note: the express broad terms of an "analogue" or a "precursor" could encompass many species of the claimed genus of an "analogue of beta-casomorphin-9" or a "precursor of beta-casomorphin 9").

Claim 32 recites the indefinite term "population". The metes and bounds of "population" cannot be delineated, as the specification fails to set forth the metes and bounds of what is encompassed. (What type of population? Is the population either of high risk or low risk of developing cardiovascular disease or Does the population already have cardiovascular disease?).

All other claims depend directly or indirectly from the rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meisel et al.,(Inhibitors of angiotensin converting enzyme derived from bovine casein, Beta-Casomorphins Relat. Pept. (Int. Symp.), 2nd (1994), 27-33) in view of Kafrissen et al. (US 6190693) as evidenced by Yunden et al. (Enzymatic release of neocasomorphin and beta-casomorphin from bovine b-casein, Peptides 20 (1999) 957-962)

Although very unclear as drafted, applicant claims a composition and/or method comprising an immunomodulating component (i.e. beta-casomorphin-9 or an analogue of beta-casomorphin-9 or A2 beta-casein) and a fortifying compound to reduce the incidence of a population with cardiovascular disease is apparently claimed.

Meisel et al teach (see, e.g. abstract) that an immunomodulating component an analogue of beta-casomorphin- 9 (i.e .the shorter analogue is bovine beta-casomorphin-7) or either beta-casein A2 modulates blood pressure and also inhibitors the Angiotensin Converting Enzyme (ACE) which is well known in the art to cause hypertension or heart failure. (also, please note that it is well known in the art that high blood pressure can cause cardiovascular disease, thus, it is important to modulate blood pressure with cardiovascular agents such as the claimed immunomodulating components. Also please note, as evidence by Yunden et al., see e.g. Introduction page 1, it states that bovine beta-casomorphin-9 is a longer analogue to bovine beta-casomorphin 7, thus, both beta-casomorphin-7 and beta-casomorphin-9 are analogues to one another). Meisel et al do not teach that a fortifying compound can treat cardiovascular diseases.

Kaffirissen et al. teach (see, e.g. claim 8) a fortifying compound such as folic acid to treat cardiovascular disorders.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Meisel et al.'s teachings to include the beneficial teachings of Kaffrissen because the combined teachings of combining the two claimed active ingredients of an immunomodulating component and a fortifying compound would

create an improved composition to reduce the incidence of population with cardiovascular disease.

Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention made, especially in the absence of evidence to the contrary.

(Please note for claims 29-31, the patentablility of a product does not depend upon its method of production. If the product in a product-by-process claim is the same or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process." (see, e.g. MPEP 2113))

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PATRICIA LEITH
PRIMARY EXAMINER